



DEPARTMENT OF HEALTH & HUMAN SERVICES

FEB 17 2010

Food and Drug Administration
Rockville MD 20857

Re: Coartem
Docket No. FDA-2009-E-0510

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 5,677,331 filed by Novartis AG, under 35 U.S.C. § 156. The human drug product claimed by the patent is Coartem (artemether/lumefantrine), which was assigned new drug application (NDA) No. N 22-268.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1).

The NDA was approved on April 7, 2009, which makes the submission of the patent term extension application on June 5, 2009, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, reading "Jane A. Axelrad", is positioned above the typed name.

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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